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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,912

09/28/2005

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EXAMINER

CHOI, PETER Y

ART UNIT

PAPER NUMBER

1771

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,912	Applicant(s) KOMURA ET AL.	
	Examiner Peter Y. Choi	Art Unit 1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/28/05, 12/23/05, 03/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

NON-FINAL ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-12, in the reply filed on July 9, 2007, is acknowledged. Claims 13-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objections

2. Claim 9 is objected to because of the following informalities: the claim recites the lower range of "(23;77)." It appears that the claim should recite "(23:77)." Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites that "any given lateral cross-section of the filaments is an irregular shape." It is unclear whether the cross-section of the aggregate of filaments is an irregular shape or whether the cross-section of each of the filaments is an irregular shape.

Regarding claim 2, the claim recites "fine pits" and "fine protrusions." It is unclear what is intended by the claimed structure and in what manner "fine" is measured in comparison.

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Regarding claim 9, the claim recites that the ratio is in the range set forth “based on weight.” It is unclear if the reference to “based on weight” is based on the weights of the solvents or the solution.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-12 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Pub. No. 2006/0057350 to Ochi.

Regarding claims 1-12, Ochi teaches a nonwoven fabric characterized by being an aggregate of filaments composed of a thermoplastic polymer, and by having a mean fiber size of 0.1-20 μ m, and a mean apparent density in the range of 10-95 kg/m³ (see entire document including paragraphs 0001, 0006, 0009, 0011, 0029, 0030, 0118, 0119, 0126, 0137, 0138, 0143, 0150, 0206, 0402, 0477).

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Regarding claims 1-12, Ochi does not appear to teach that any given lateral cross-section of the filaments is an irregular shape. However, as best Examiner can determine, the irregular shape is due to the process by which the filaments are made. Although the prior art does not disclose the irregular shaped lateral cross-section, the claimed structure is deemed to be inherent to the process set forth in the prior art since the Ochi reference teaches a similar structural and chemical composition as the claimed invention made by a substantially similar process (electrospinning a thermoplastic with a solvent as set forth in paragraphs 0460, 0471, 484-488). The burden is on the Applicants to prove otherwise.

Regarding claim 2, Ochi does not appear to teach that the irregular shape is at least one type selected from the group consisting of fine pits on the filament surfaces, fine protrusions on the filament surfaces, pits formed in a linear fashion in the fiber axis direction on the filament surfaces, protrusions formed in a linear fashion in the fiber axis direction on the filament surfaces and micropores in the filament surfaces. However, as best Examiner can determine, the claimed irregular shapes are due to the process by which the filaments are made. Although the prior art does not disclose the claimed irregular shapes, the claimed structures are deemed to be inherent to the process set forth in the prior art since the Ochi reference teaches a similar structural and chemical composition as the claimed invention made by a substantially similar process (electrospinning a thermoplastic with a solvent as set forth in paragraphs 0460, 0471, 484-488). The burden is on the Applicants to prove otherwise.

Regarding claim 3, the mean fiber size is 0.1-5 μm (paragraphs 0119, 0206).

Regarding claim 4, the nonwoven fabric thickness is 100 μm or greater (paragraphs 0402, 0477).

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Regarding claims 5-12, the thermoplastic polymer is a polymer which is soluble in a volatile solvent (paragraphs 0118, 0150, 0460).

Regarding claim 6, the thermoplastic polymer which is soluble in a volatile solvent is an aliphatic polyester (paragraphs 0118, 0150, 0460).

Regarding claim 7, the aliphatic polyester is polylactic acid (paragraphs 0118, 0150, 0460).

Regarding claims 8-12, Ochi does not appear to teach that the volatile solvent is a mixed solvent comprising a volatile good solvent and a volatile poor solvent, that the ratio of the volatile poor solvent and volatile good solvent in said mixed solvent is in the range of (23:77) to (40:60), based on weight, that the volatile good solvent is a halogen-containing hydrocarbon, that the volatile poor solvent is a lower alcohol, and that the lower alcohol is ethanol. However, the prior art invention appears to meet the claim limitations as the thermoplastic polymer in the prior art is the same as the claimed thermoplastic polymer and appears to be soluble in the a halogen-containing hydrocarbon and ethanol (paragraphs 0118, 0150, 0460, 0471, 484-488).

In the event it is shown that Ochi does not disclose the claimed invention with sufficient specificity, the invention is obvious because Ochi discloses the claimed constituents and discloses that they may be used in combination.

Claim Rejections - 35 USC § 103

7. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pub. No. 2002/0192449 to Hobbs in view of USPN 4,701,267 to Watanabe.

Regarding claims 1-12, Hobbs teaches a nonwoven fabric characterized by being an aggregate of filaments composed of a thermoplastic polymer, and by having a mean fiber size of 0.1-20 μm , wherein any given lateral cross-section of the filaments is an irregular shape (see entire document including paragraphs 0001, 0010-0017, 0030, 0047, 0070, 0107-0110, 0114, 0116, 0118, 0121).

Regarding claims 1-12, Hobbs does not appear to teach that the fabric has a mean apparent density in the range of 10-95 kg/m^3 . Since Hobbs is silent with regards to specific density of the fabric, it would have been necessary and thus obvious to look to the prior art for conventional specifications. Watanabe provides this conventional teaching showing that it is known in the medical industry fabric art to form a nonwoven fabric comprising thermoplastic microfibers wherein the density of the fabric is from 0.01 g/cm^3 to 0.7 g/cm^3 (Watanabe, column 2 lines 5-22, column 3 lines 5-18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the nonwoven microfiber fabric of Hobbs having a fabric density of from 0.01 g/cm^3 to 0.7 g/cm^3 , as taught by Watanabe, motivated by the expectation of forming a conventional medical industry fabric according to specifications known in the art which are suitable for the desired application as a wound dressing or filter.

Regarding claim 2, the irregular shape is at least one type selected from the group consisting of fine pits on the filament surfaces, fine protrusions on the filament surfaces, pits formed in a linear fashion in the fiber axis direction on the filament surfaces, protrusions formed in a linear fashion in the fiber axis direction on the filament surfaces and micropores in the filament surfaces (Hobbs, paragraphs 0010, 0011, 0021).

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Regarding claim 3, the mean fiber size is 0.1-5 μm (paragraphs 0010, 0015).

Regarding claim 4, the nonwoven fabric thickness is 100 μm or greater (paragraphs 0047, 0070, Claim 41).

Regarding claims 5-12, the thermoplastic polymer is a polymer which is soluble in a volatile solvent (paragraph 0030).

Regarding claim 6, the thermoplastic polymer which is soluble in a volatile solvent is an aliphatic polyester (paragraph 0030).

Regarding claim 7, the aliphatic polyester is polylactic acid (paragraph 0030).

Regarding claims 8-12, Hobbs in view of Watanabe does not appear to teach that the volatile solvent is a mixed solvent comprising a volatile good solvent and a volatile poor solvent, that the ratio of the volatile poor solvent and volatile good solvent in said mixed solvent is in the range of (23:77) to (40:60), based on weight, that the volatile good solvent is a halogen-containing hydrocarbon, that the volatile poor solvent is a lower alcohol, and that the lower alcohol is ethanol. However, the prior art invention appears to meet the claim limitations as the thermoplastic polymer in the prior art is the same as the claimed thermoplastic polymer and appears to be soluble in the a halogen-containing hydrocarbon and ethanol (paragraph 0030).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Y. Choi whose telephone number is (571) 272-6730. The examiner can normally be reached on Monday - Friday, 08:00 - 15:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter Y. Choi/
Examiner, Art Unit 1771
July 31, 2007

/Andrew T Piziali/
Primary Examiner, Art Unit 1771